

Calendar No. 454

103D CONGRESS
2D SESSION

S. 2129

To amend title 18, United States Code, to preserve personal privacy with respect to medical records and health care-related information, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 18 (legislative day, MAY 16), 1994

Mr. LEAHY (for himself, Mr. RIEGLE, and Mr. WOFFORD) introduced the following bill; which was read the first time

JUNE 7, 1994

Read the second time and placed on the calendar

A BILL

To amend title 18, United States Code, to preserve personal privacy with respect to medical records and health care-related information, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Health Care Privacy
5 Protection Act".

1 **SEC. 2. FINDINGS AND PURPOSES.**

2 (a) **FINDINGS.**—The Congress finds as follows:

3 (1) The right to privacy is a personal and fun-
4 damental right protected by the Constitution of the
5 United States.

6 (2) The improper disclosure of personally iden-
7 tifiable health care information may cause signifi-
8 cant harm to a person's interest in privacy, health
9 care, and reputation and may unfairly affect the
10 ability of a person to obtain employment, education,
11 insurance, and credit.

12 (3) The movement of people and health care-re-
13 lated information across State lines, availability of
14 access to and exchange of health care-related infor-
15 mation from automated data banks and networks,
16 and emergence of multistate health care providers
17 and payors create a need for uniform Federal law
18 governing the disclosure of health care information.

19 (b) **PURPOSE.**—The purpose of this Act is to estab-
20 lish effective mechanisms to protect the privacy of persons
21 with respect to personally identifiable health care informa-
22 tion that is created or maintained as part of health treat-
23 ment, enrollment, payment, or testing processes.

TITLE I—JUDICIAL PROCEEDINGS

SEC. 101. PRIVACY OF PERSONALLY IDENTIFIABLE HEALTH CARE INFORMATION.

(a) OFFENSE.—Part I of title 18, United States Code, is amended by inserting after chapter 84, the following new chapter:

“CHAPTER 84A—PRIVACY OF PERSON- ALLY IDENTIFIABLE HEALTH CARE IN- FORMATION

“Sec.

“1755. Wrongful disclosure of personally identifiable health care information.

“1756. Misuse of health security card or unique identifier.

“§ 1755. Wrongful disclosure of protected health in- formation

“(a) DEFINITIONS.—

“(1) PROTECTED HEALTH INFORMATION.—The term “protected health information” means any information, whether oral or recorded in any form or medium, that—

“(A)(i) is created or received by a health care provider, health benefit plan, health oversight agency, public health authority, or regional data center; or

1 “(ii) is created or received by an employer
2 through the process of testing or screening ap-
3 plicants or employees; and

4 “(B) relates to the past, present, or future
5 physical or mental health or condition of an in-
6 dividual, the provision of health care to an indi-
7 vidual or payment for the provision of health to
8 an individual and—

9 “(i) identifies the individual; or

10 “(ii) with respect to which there is a
11 reasonable basis to believe that the infor-
12 mation can be used to identify the individ-
13 ual.

14 “(2) HEALTH CARE.—The term ‘health care’—

15 “(A) means—

16 “(i) a preventative, diagnostic, thera-
17 peutic rehabilitative, maintenance, or pal-
18 liative care, counseling, service, or
19 procedure—

20 “(I) with respect to the physical
21 or mental condition of an individual;
22 or

23 “(II) affecting the structure of
24 function of the human body or any
25 part of the human body; or

1 “(ii) any sale or dispensing of a drug,
2 device, equipment, or other item to an indi-
3 vidual, or for the use of an individual, pur-
4 suant to a prescription; and

5 “(B) does not include any item or service
6 that is not furnished for the purpose of examin-
7 ing, maintaining or improving the health of an
8 individual.

9 “(b) OFFENSE.—A person who knowingly—

10 “(1) obtains protected health information relat-
11 ing to an individual in violation of title II of the
12 Health Care Privacy Protection Act; or

13 “(2) discloses protected health information to
14 another person in violation of title II of the Health
15 Care Privacy Protection Act,

16 shall be punished as provided in subsection (c).

17 “(c) PENALTIES.—A person who violates subsection
18 (b) shall—

19 “(1) be fined not more than \$50,000, impris-
20 oned not more than 1 year, or both;

21 “(2) if the offense is committed under false pre-
22 tenses, be fined not more than \$100,000, imprisoned
23 not more than 5 years, or both; and

24 “(3) if the offense is committed with intent to
25 sell, transfer, or use protected health information for

1 commercial advantage, personal gain, or malicious
 2 harm, fined not more than \$250,000, imprisoned not
 3 more than 10 years, or both.

4 **“§ 1756. Misuse of health security card or unique**
 5 **identifier**

6 “A person who—

7 “(1) requires the display of, requires the use of,
 8 or uses a health security card that is issued under
 9 section 1001(b) of the Health Security Act for any
 10 purpose other than a purpose described in section
 11 5105(a) of that Act; or

12 “(2) requires the disclosure of, requires the use
 13 of, or uses a unique identifier number provided
 14 under section 5104 of that Act for any purpose that
 15 is not authorized by the National Health Board pur-
 16 suant to that section,

17 shall be fined not more than \$25,000, imprisoned not
 18 more than 2 years, or both.”.

19 (b) TECHNICAL AMENDMENT.—The part analysis for
 20 part I of title 18, United States Code, is amended by in-
 21 serting after the item related to chapter 84, the following
 22 new item:

“84A. Privacy of personally identifiable health care information 1755.”.

1 **TITLE II—LIMITATIONS ON DIS-**
2 **CLOSURE OF PROTECTED**
3 **HEALTH INFORMATION**

4 **SEC. 201. DEFINITIONS.**

5 In this title:

6 (1) **HEALTH BENEFIT PLAN.**—The term
7 “health benefit plan” means a public or private en-
8 tity or program that provides payments for health
9 care or that provides life insurance—

10 (A) including—

11 (i) a group health plan (as defined in
12 section 607 of the Employee Retirement
13 Income Security Act of 1974 (29 U.S.C.
14 1167)), employer self-insurance plan, or a
15 multiple employer welfare arrangement (as
16 defined in section 3 of that Act (29 U.S.C.
17 1002)) providing health benefits;

18 (ii) any other health insurance ar-
19 rangement, including any arrangement
20 consisting of a hospital or medical expense
21 incurred policy or certificate, hospital or
22 medical service plan contract, health main-
23 tenance organization subscriber contract;
24 and

25 (iii) a life insurance plan;

1 (B) but not including—

2 (i) an individual who makes a pay-
3 ment on the individual's own behalf (or on
4 behalf of any other individual) for health
5 care or for deductibles, coinsurance,
6 copayments, items, or services not covered
7 under a health insurance arrangement;

8 (ii) a plan sponsor (as defined in sec-
9 tion 3 of the Employee Retirement Income
10 Security Act of 1974 (29 U.S.C. 1002));

11 (iii) an employer of an employee cov-
12 ered under a multiple employer welfare ar-
13 rangement;

14 (iv) an employee organization that
15 sponsors a multiple employer welfare ar-
16 rangement; or

17 (v) an organization, association, com-
18 mittee, joint board of trustees, or similar
19 group of representatives of 2 or more em-
20 ployers described in clause (iii) or 2 or
21 more employee organizations described in
22 clause (iv).

23 (2) HEALTH CARE.—The term “health care”—

24 (A) means—

1 (i) a preventative, diagnostic, thera-
2 peutic, rehabilitative, maintenance, or pal-
3 liative care, counseling, service, or
4 procedure—

5 (I) with respect to the physical or
6 mental condition of an individual; or

7 (II) affecting the structure or
8 function of the human body or any
9 part of the human body; or

10 (ii) any sale or dispensing of a drug,
11 device, equipment, or other item to an indi-
12 vidual, or for the use of an individual, pur-
13 suant to a prescription; but

14 (B) does not include any item or service
15 that is not furnished for the purpose of examin-
16 ing, maintaining, or improving the health of an
17 individual.

18 (3) HEALTH CARE PROVIDER.—The term
19 “health care provider” means a person who is li-
20 censed, certified, registered, or otherwise authorized
21 by law to provide an item or service that constitutes
22 health care in the ordinary course of business or
23 practice of a profession.

24 (4) HEALTH INFORMATION TRUSTEE.—The
25 term “health information trustee” means—

1 (A) a health care provider, health benefit
2 plan, health oversight agency, regional data
3 center, or employer, insofar as it creates, re-
4 ceives, maintains, uses, or transmits protected
5 health information; and

6 (B) any person who obtains protected
7 health information under section 207, 208, 209,
8 210, 211, 212, or 215.

9 (5) HEALTH OVERSIGHT AGENCY.—The term
10 “health oversight agency” means a person that—

11 (A) performs or oversees the performance
12 of an assessment, evaluation, determination, or
13 investigation relating to the licensing, accredita-
14 tion, or certification of health care providers; or

15 (B)(i) performs or oversees the perform-
16 ance of an assessment, evaluation, determina-
17 tion, or investigation relating to the effective-
18 ness of, compliance with, or applicability of
19 legal, fiscal, medical, or scientific standards or
20 aspects of performance related to the delivery
21 of, or payment for, health care or relating to
22 health care fraud or fraudulent claims for pay-
23 ment regarding health; and

24 (ii) is a public agency, acting on behalf of
25 a public agency, acting pursuant to a require-

1 ment of a public agency, or carrying out activi-
2 ties under a Federal or State statute governing
3 the assessment, evaluation, determination, or
4 investigation.

5 (6) HEALTH RESEARCHER.—The term “health
6 researcher” means a person who conducts a bio-
7 medical, epidemiological, or health services research
8 project or a health statistics project that has been
9 approved by—

10 (A) an institutional review board for the
11 organization sponsoring the project;

12 (B) an institutional review board for each
13 health information trustee that maintains pro-
14 tected health information intended to be used in
15 the project; or

16 (C) an institutional review board estab-
17 lished or designated by the Secretary.

18 (7) INSTITUTIONAL REVIEW BOARD.—The term
19 “institutional review board” means—

20 (A) a board established in accordance with
21 regulations of the Secretary under section
22 491(a) of the Public Health Service Act (42
23 U.S.C. 289);

1 (B) a similar board established by the Sec-
2 retary for the protection of human subjects in
3 research conducted by the Secretary; or

4 (C) a similar board established under regu-
5 lations of a Federal Government authority other
6 than the Secretary.

7 (8) LAW ENFORCEMENT INQUIRY.—The term
8 “law enforcement inquiry” means an investigation or
9 official proceeding inquiring into whether there is a
10 violation of, or failure to comply with, any criminal
11 or civil statute or any regulation, rule, or order is-
12 sued pursuant to such a statute.

13 (9) PERSON.—The term “person” includes an
14 authority of the United States, a State, or a political
15 subdivision of a State.

16 (10) PROTECTED HEALTH INFORMATION.—The
17 term “protected health information” means any in-
18 formation, whether oral or recorded in any form or
19 medium, that—

20 (A)(i) is created or received by a health
21 care provider, health benefit plan, health over-
22 sight agency, public health authority, or re-
23 gional data center; or

(ii) is created or received by an employer through the process of testing or screening applicants or employees; and

(B) relates to the past, present, or future physical or mental health or condition of a person, the provision of health care to a person, or payment for the provision of health care to an individual and—

(i) identifies the individual; or

(ii) with respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

(11) PUBLIC HEALTH AUTHORITY.—The term “public health authority” means an authority or instrumentality of the United States, a State, or a political subdivision of a State that is (A) responsible for public health matters; and (B) engaged in such activities as injury reporting, public health surveillance, and public health investigation or intervention.

(12) REGIONAL DATA CENTER.—The term “regional data center” means—

1 (A) an entity established in accordance
2 with the Health Security Act and designated as
3 such by the Secretary;

4 (B) an entity that receives, maintains,
5 uses, or transmits information regarding health
6 for payment, statistical, or research purposes.

7 (13) SECRETARY.—The term “Secretary”
8 means the Secretary of Health and Human Services.

9 (14) STATE.—The term “State” includes the
10 District of Columbia, Puerto Rico, the Virgin Is-
11 lands, Guam, American Samoa, and the Northern
12 Mariana Islands.

13 **SEC. 202. GENERAL LIMITATIONS ON DISCLOSURE.**

14 (a) IN GENERAL.—

15 (1) DISCLOSURE WITHIN A TRUSTEE.—A
16 health information trustee may disclose protected
17 health information to an officer, employee, or agent
18 of the trustee only for a purpose that is compatible
19 with and related to the purpose for which the
20 information—

21 (A) was collected; or

22 (B) was received by that trustee.

23 (2) DISCLOSURE OUTSIDE A TRUSTEE.—A
24 health information trustee may disclose protected
25 health information to a person other than an officer,

1 employee, or agent of the trustee only for a purpose
2 that is authorized under this Act.

3 (3) SCOPE OF DISCLOSURE.—

4 (A) IN GENERAL.—Every disclosure of pro-
5 tected health information by a health informa-
6 tion trustee shall be limited to the minimum
7 amount of information necessary to accomplish
8 the purpose for which the information is dis-
9 closed.

10 (B) GUIDELINES.—Not later than July 1,
11 1996, the Attorney General, in consultation
12 with the Secretary, after notice and opportunity
13 for public comment, shall issue guidelines to im-
14 plement subparagraph (A), which shall take
15 into account the technical capabilities of the
16 record systems used to maintain protected
17 health information and the costs of limiting dis-
18 closure.

19 (4) IDENTIFICATION OF DISCLOSED INFORMA-
20 TION AS PROTECTED INFORMATION.—Except with
21 respect to protected health information that is dis-
22 closed under section 217, and except as provided in
23 paragraph (5), a health information trustee may not
24 disclose protected health information unless such in-

1 formation is clearly identified as protected health in-
2 formation that is subject to this section.

3 (5) ROUTINE DISCLOSURES SUBJECT TO WRIT-
4 TEN AGREEMENT.—A health information trustee
5 who routinely discloses protected health information
6 to a person may satisfy the identification require-
7 ment in paragraph (4) through a written agreement
8 between the trustee and the person with respect to
9 the protected health information.

10 (6) AGREEMENT TO LIMIT DISCLOSURE.—A
11 health information trustee who receives protected
12 health information from any person pursuant to a
13 written agreement to restrict disclosure of the infor-
14 mation to a greater extent than would otherwise be
15 required under this section shall comply with the
16 terms of the agreement, except in circumstances in
17 which disclosure of the information is required by
18 law notwithstanding the agreement.

19 (7) NO GENERAL REQUIREMENT TO DIS-
20 CLOSE.—Except as provided in the section 217 re-
21 lating to inspection, nothing in this section shall be
22 construed to require a health information trustee to
23 disclose protected health information not otherwise
24 required to be disclosed by law.

1 cally named or generically described in the author-
2 ization as a person to whom such information may
3 be disclosed.

4 (5) STATEMENT OF INTENDED DISCLOSURES.—

5 The authorization contains an acknowledgment that
6 the individual who is the subject of the information
7 has received a statement of the disclosures that the
8 person to receive the protected health information
9 intends to make, which statement shall be in writ-
10 ing, on a form that is distinct from the authorization
11 for disclosure, and which statement must be received
12 by the individual authorizing the disclosure on or be-
13 fore such authorization is executed.

14 (6) INFORMATION DESCRIBED.—The informa-
15 tion to be disclosed is described in the authorization.

16 (7) AUTHORIZATION TIMELY RECEIVED.—The
17 authorization is received by the trustee during a pe-
18 riod described in subsection (c)(1).

19 (8) DISCLOSURE TIMELY MADE.—The disclo-
20 sure occurs during a period described in subsection
21 (c)(2).

22 (b) AUTHORIZATIONS REQUESTED IN CONNECTION
23 WITH PROVISION OF HEALTH CARE.—

24 (1) IN GENERAL.—A health information trustee
25 may not request that an individual person provide to

1 any other person an authorization described in sub-
2 section (a) on a day on which—

3 (A) the trustee provides health care to the
4 individual requested to provide the authoriza-
5 tion; or

6 (B) in the case of a trustee that is a health
7 facility, the individual is admitted into the facil-
8 ity as a resident or inpatient in order to receive
9 health care.

10 (2) EXCEPTION.—Paragraph (1) does not apply
11 if a health information trustee requests that an indi-
12 vidual provide an authorization described in sub-
13 section (a) for the purpose of assisting the individual
14 in obtaining counseling or social services from a per-
15 son other than the trustee.

16 (c) TIME LIMITATIONS ON AUTHORIZATIONS.—

17 (1) RECEIPT BY TRUSTEE.—For purposes of
18 subsection (a)(7), an authorization is timely received
19 if it is received by the trustee during—

20 (A) the 1-year period beginning on the
21 date on which the authorization is signed under
22 subsection (a)(1), if the authorization permits
23 the disclosure of protected health information to
24 a person who provides health counseling or so-
25 cial services to individuals; or

1 that the individual may have under common or statutory
2 law in a court of a State or the United States.

3 (g) ADDITIONAL REQUIREMENTS OF TRUSTEE.—A
4 health information trustee may impose requirements for
5 an authorization that are in addition to the requirements
6 in this subsection.

7 (h) COPY.—A health information trustee who dis-
8 closes protected health information pursuant to an author-
9 ization under this section shall maintain a copy of the au-
10 thorization as part of the information.

11 (i) RULE OF CONSTRUCTION.—This section shall not
12 be construed—

13 (1) to require a health information trustee to
14 disclose protected health information; or

15 (2) to limit the right of a health information
16 trustee to charge a fee for the disclosure or repro-
17 duction of protected health information.

18 (j) SUBPOENAS.—If a health information trustee dis-
19 closes protected health information pursuant to an author-
20 ization in order to comply with a subpoena, the
21 authorization—

22 (1) shall specifically authorize the disclosure for
23 the purpose of permitting the trustee to comply with
24 the subpoena; and

1 (2) shall otherwise meet the requirements in
2 this subsection.

3 **SEC. 204. TREATMENT AND PAYMENT.**

4 (a) IN GENERAL.—(1) A health care provider, health
5 benefit plan, employer, or person that receives protected
6 health information under section 208 may disclose pro-
7 tected health information to a health care provider for the
8 purpose of providing health care to an individual and the
9 individual who is the subject of the information has not
10 previously objected to the disclosure in writing.

11 (2) A health care provider, health benefit plan, em-
12 ployer, regional data center or person that receives pro-
13 tected health information under section 208 may disclose
14 protected health information to a health benefit plan for
15 the purpose of providing for the payment for health care
16 furnished to an individual.

17 (3) A health care provider, or health benefit plan or
18 person that receives protected health information under
19 section 208 may disclose protected health information to
20 a regional data center for the purpose of carrying out its
21 functions.

22 (b) SCOPE OF DISCLOSURE.—The disclosure of pro-
23 tected health information under this section shall be lim-
24 ited to the minimum amount necessary to accomplish the
25 purpose for which the disclosure is authorized.

1 (1) the individual who is the subject of the in-
2 formation has not previously objected to the disclo-
3 sure after being notified of the right to object; and

4 (2) the information disclosed relates to health
5 care currently being provided to that individual.

6 (b) DIRECTORY INFORMATION.—A health care pro-
7 vider and a person receiving protected health information
8 under section 208 may disclose information to any person
9 if—

10 (1) the information does not reveal specific in-
11 formation about the physical or mental condition of
12 the individual who is the subject of the information
13 or health care provided to that person;

14 (2) the individual who is the subject of the in-
15 formation has not objected in writing to the disclo-
16 sure after being notified of the right to object; and

17 (3) the information consists only of 1 or more
18 of the following items:

19 (A) The name of the individual who is the
20 subject of the information.

21 (B) If the individual who is the subject of
22 the information is receiving health care from a
23 health care provider on a premises controlled by
24 the provider—

1 (i) the location of the individual on
2 the premises; and

3 (ii) the general health status of the in-
4 dividual, described as critical, poor, fair,
5 stable, or satisfactory or in terms denoting
6 similar conditions.

7 (c) IDENTIFICATION OF DEAD PERSON.—A health
8 information trustee may disclose protected health informa-
9 tion if necessary to assist in the identification of a dead
10 person.

11 **SEC. 207. PUBLIC HEALTH.**

12 (a) IN GENERAL.—A health care provider, health
13 benefit plan, public health authority, employer, or person
14 that receives protected health information under section
15 208 may disclose protected health information to a public
16 health authority or other person authorized by law for use
17 in legally authorized—

- 18 (1) disease or injury reporting;
19 (2) public health surveillance; or
20 (3) public health investigation or intervention.

21 (b) SCOPE OF DISCLOSURE.—The disclosure of pro-
22 tected health information under this section shall be lim-
23 ited to the minimum amount necessary to accomplish the
24 purpose for which the disclosure is authorized.

1 **SEC. 208. EMERGENCY CIRCUMSTANCES.**

2 (a) IN GENERAL.—A health care provider, health
3 benefit plan, employer, or person that receives protected
4 health information under section 208 may disclose pro-
5 tected health information in emergency circumstances
6 when necessary to protect the health or safety of an indi-
7 vidual from imminent harm.

8 (b) SCOPE OF DISCLOSURE.—The disclosure of pro-
9 tected health information under this section shall be lim-
10 ited to the minimum amount necessary to accomplish the
11 purpose for which the disclosure is authorized and shall
12 be limited to persons who need the information to protect
13 the health or safety of the individual.

14 (c) USE IN ACTION AGAINST INDIVIDUAL.—Pro-
15 tected health information about an individual that is dis-
16 closed under this section may not be used in, or disclosed
17 to any person for use in, any administrative, civil, or crimi-
18 nal action or investigation directed against the individual
19 except when the use or disclosure is authorized by law for
20 protection of the public health.

21 **SEC. 209. JUDICIAL AND ADMINISTRATIVE PURPOSES.**

22 (a) IN GENERAL.—A health care provider, health
23 benefit plan, health oversight agency, employer, and per-
24 son that receives protected health information under sec-
25 tion 208 may disclose protected health information—

1 (1) pursuant to the Federal Rules of Civil Pro-
2 cedure, the Federal Rules of Criminal Procedure, or
3 comparable rules of other courts or administrative
4 agencies in connection with litigation or proceedings
5 to which the individual who is the subject of the in-
6 formation is a party and in which the individual has
7 placed the individual's physical or mental condition
8 in issue;

9 (2) if ordered by a court in connection with an
10 examination of an individual; or

11 (3) pursuant to a law requiring the reporting of
12 specific medical information to law enforcement au-
13 thorities.

14 (b) SCOPE OF DISCLOSURE.—The disclosure of pro-
15 tected health information under this section shall be lim-
16 ited to the minimum amount necessary to accomplish the
17 purpose for which the disclosure is authorized.

18 (c) LIMIT ON ADDITIONAL DISCLOSURE.—A person
19 that receives protected health information under this sec-
20 tion may use the information and disclose such informa-
21 tion only for the purpose for which it was received.

22 **SEC. 210. HEALTH RESEARCH.**

23 (a) IN GENERAL.—A health information trustee may
24 disclose protected health information to a health re-
25 searcher if the disclosure is for use in a health research

1 project that has been determined by an institutional re-
2 view board to be—

3 (1) of sufficient importance to outweigh the in-
4 trusion into the privacy of the individual who is the
5 subject of the information that would result from the
6 disclosure; and

7 (2) necessary for the effectiveness of the
8 project.

9 (b) OBLIGATIONS OF RECIPIENT.—A person who re-
10 ceives protected health information pursuant to subsection
11 (a)—

12 (1) shall remove or destroy, at the earliest op-
13 portunity consistent with the purposes of the project,
14 information that would enable an individual to be
15 identified, unless—

16 (A) an institutional review board has de-
17 termined that there is a health or research jus-
18 tification for retention of such identifiers; and

19 (B) there is an adequate plan to protect
20 the identifiers from disclosure that is inconsis-
21 tent with this section.

22 (2) shall use protected health information solely
23 for purposes of the health research project for which
24 disclosure was authorized under this section.

1 (c) SCOPE OF DISCLOSURE.—The disclosure of pro-
2 tected health information under this section shall be lim-
3 ited to the minimum amount necessary to accomplish the
4 research purpose for which the disclosure is authorized.

5 (d) RESEARCH REQUIRING DIRECT CONTACT.—Pro-
6 tected health information may not be disclosed to a health
7 researcher for a research project that includes direct con-
8 tact with an individual who is the subject of protected
9 health information unless the individual who is the subject
10 of the protected health information has been given notice
11 by the health information trustee that such contact is pos-
12 sible and been given the opportunity to object to the dis-
13 closure and the individual has not objected.

14 **SEC. 211. LAW ENFORCEMENT.**

15 (a) IN GENERAL.—A health care provider, health
16 benefit plan, health oversight agency, health researcher,
17 employer, or other person that receives protected health
18 information under section 208 may disclose protected
19 health information to a law enforcement agency (other
20 than a health oversight agency governed by section 205)
21 if the information is requested for use—

22 (1) in an investigation or prosecution of a
23 health information trustee;

1 (2) in the identification or location of a victim,
2 suspect, fugitive, or witness in a law enforcement in-
3 quiry; or

4 (3) in connection with the investigation of
5 criminal activity committed against the trustee or on
6 premises controlled by the trustee.

7 (b) CERTIFICATION.—When a law enforcement agen-
8 cy (other than a health oversight agency) requests a health
9 information trustee disclose protected health information
10 under this subsection, the law enforcement agency shall
11 provide the trustee with a written certification that—

12 (1) specifies the information requested;

13 (2) states that the information is needed for a
14 lawful purpose under this section; and

15 (3) is signed by a supervisory official of a rank
16 designated by the head of the agency.

17 (c) SCOPE OF DISCLOSURE.—The disclosure of pro-
18 tected health information under this section shall be lim-
19 ited to the minimum amount necessary to accomplish the
20 purpose for which the disclosure is authorized.

21 (d) RESTRICTIONS ON ADDITIONAL DISCLOSURE.—
22 Protected health information about an individual that is
23 disclosed to a law enforcement agency under this section—

24 (1) may not be disclosed for, or used in, any
25 administrative, civil, or criminal action or investiga-

1 tion against the individual, except in an action or in-
2 vestigation arising out of and directly related to the
3 action or investigation for which the information was
4 obtained; and

5 (2) may not be otherwise used or disclosed by
6 the law enforcement agency, unless the use or disclo-
7 sure is necessary to fulfill the purpose for which the
8 information was obtained and is not otherwise pro-
9 hibited by law.

10 **SEC. 212. SUBPOENAS AND WARRANTS.**

11 (a) IN GENERAL.—A health care provider, health
12 benefit plan, health oversight agency, employer, or person
13 that receives protected health information under section
14 208 may disclose protected health information under this
15 section if the disclosure is pursuant to—

16 (1) a subpoena issued under the authority of a
17 grand jury, and the trustee is provided a written cer-
18 tification by the grand jury seeking the information
19 that the grand jury has complied with the applicable
20 access provisions of section 213;

21 (2) an administrative subpoena or a judicial
22 subpoena or warrant, and the trustee is provided a
23 written certification by the person seeking the infor-
24 mation that the person has complied with the appli-
25 cable access provisions of section 213 or 214; or

1 (3) an administrative subpoena or a judicial
2 subpoena or warrant, and the disclosure otherwise
3 meets the conditions of section 205, 207, 208, 209,
4 or 211.

5 (b) RESTRICTIONS ON ADDITIONAL DISCLOSURE.—
6 Protected health information about an individual that is
7 received under—

8 (1) subsection (a) may not be disclosed for, or
9 used in, any administrative, civil, or criminal action
10 or investigation against the individual, except in an
11 action or investigation arising out of and directly re-
12 lated to the inquiry for which the information was
13 obtained;

14 (2) subsection (a)(2) may not be otherwise dis-
15 closed by the recipient unless the disclosure is nec-
16 essary to fulfill the purpose for which the informa-
17 tion was obtained; and

18 (3) subsection (a)(3) may not be disclosed by
19 the recipient unless the recipient complies with the
20 conditions and restrictions on disclosure with which
21 the recipient would have been required to comply if
22 the disclosure had been made under section 205,
23 207, 208, 209, or 211.

1 **SEC. 213. ACCESS PROCEDURES FOR LAW ENFORCEMENT**
2 **SUBPOENAS AND WARRANTS.**

3 (a) **PROBABLE CAUSE REQUIREMENT.**—A govern-
4 ment authority may not obtain protected health informa-
5 tion about a person under section 212(a) (1) or (2) for
6 use in a law enforcement inquiry unless there is probable
7 cause to believe that the information is relevant to a legiti-
8 mate law enforcement inquiry being conducted by the gov-
9 ernment authority.

10 (b) **WARRANTS.**—A government authority that ob-
11 tains protected health information about an individual
12 under circumstances described in subsection (a) and pur-
13 suant to a warrant shall, not later than 30 days after the
14 date the warrant was executed, serve the individual with,
15 or mail to the last known address of the individual, a no-
16 tice that protected health information about the individual
17 was so obtained.

18 (c) **SUBPOENAS.**—Except as provided in subsection
19 (d), a government authority may not obtain protected
20 health information about an individual under cir-
21 cumstances described in subsection (a) and pursuant to
22 a subpoena unless a copy of the subpoena has been served
23 on the individual on or before the date of return of the
24 subpoena, together with a notice of the individual's right
25 to challenge the subpoena in accordance with section 214,
26 and—

1 (1) 30 days have passed from the date of serv-
2 ice on the individual and within that time period the
3 individual has not initiated a challenge in accordance
4 with section 214; or

5 (2) disclosure is ordered by a court after chal-
6 lenge under section 214.

7 (d) APPLICATION FOR DELAY.—

8 (1) IN GENERAL.—A government authority may
9 apply ex parte and under seal to an appropriate
10 court to delay (for an initial period of not longer
11 than 90 days) serving a copy of a subpoena or notice
12 required under subsection (b) or (c) with respect to
13 a law enforcement inquiry. The government author-
14 ity may apply to the court for extensions of the
15 delay.

16 (2) REASONS FOR DELAY.—An application for
17 a delay, or extension of a delay, under this sub-
18 section shall state, with reasonable specificity, the
19 reasons why the delay or extension is being sought.

20 (3) EX PARTE ORDER.—The court shall enter
21 an ex parte order delaying, or extending the delay
22 of, notice and an order prohibiting the disclosure of
23 the request for or disclosure of the protected health
24 information and an order requiring the disclosure of

1 the protected health information if the court finds
2 that—

3 (A) the inquiry being conducted is within
4 the lawful jurisdiction of the government au-
5 thority seeking the protected health informa-
6 tion;

7 (B) there is probable cause to believe that
8 the protected health information being sought is
9 relevant to a legitimate law enforcement in-
10 quiry;

11 (C) the government authority's need for
12 the information outweighs the privacy interest
13 of the individual who is the subject of the infor-
14 mation; and

15 (D) there is reasonable ground to believe
16 that receipt of notice by the individual will re-
17 sult in—

18 (i) endangering the life or physical
19 safety of any individual;

20 (ii) flight from prosecution;

21 (iii) destruction of or tampering with
22 evidence or the information being sought;
23 or

24 (iv) intimidation of potential wit-
25 nesses.

1 (c) PROCEEDINGS.—The government authority may
2 file with the court such papers, including affidavits and
3 other sworn documents, as sustain the validity of the sub-
4 poena. The movant may file with the court reply papers
5 in response to the authority's filing. The court, upon the
6 request of the movant or the government authority or
7 both, may proceed in camera. The court may conduct such
8 proceedings as it deems appropriate to rule on the motion,
9 but shall endeavor to expedite its determination.

10 (d) STANDARD FOR DECISION.—A court may deny
11 a motion under subsection (a) if it finds there is probable
12 cause to believe the protected health information being
13 sought is relevant to a legitimate law enforcement inquiry
14 being conducted by the government authority, unless the
15 court finds the movant's privacy interest outweighs the
16 government authority's need for the information. The
17 movant shall have the burden of demonstrating that the
18 individual's privacy interest outweighs the need estab-
19 lished by the government authority for the information.

20 (e) SPECIFIC CONSIDERATIONS WITH RESPECT TO
21 PRIVACY INTEREST.—In reaching its determination, the
22 court shall consider—

23 (1) the particular purpose for which the infor-
24 mation was collected;

1 (2) the degree to which disclosure of the infor-
2 mation will embarrass, injure, or invade the privacy
3 of the movant;

4 (3) the effect of the disclosure on the movant's
5 future health care;

6 (4) the importance of the inquiry being con-
7 ducted by the government authority, and the impor-
8 tance of the information to that inquiry; and

9 (5) any other factor deemed relevant by the
10 court.

11 (f) ATTORNEY'S FEES.—In the case of a motion
12 brought under subsection (a) in which the movant sub-
13 stantially prevails, the court may assess against the gov-
14 ernment authority a reasonable attorney's fee and other
15 litigation costs (including expert fees) reasonably incurred.

16 (g) NO INTERLOCUTORY APPEAL.—A ruling denying
17 a motion to quash under this section shall not be deemed
18 to be a final order, and no interlocutory appeal may be
19 taken therefrom by the movant. An appeal of such a ruling
20 may be taken by the movant within such period of time
21 as is provided by law as part of any appeal from a final
22 order in any legal proceeding initiated against the movant
23 arising out of or based upon the protected health informa-
24 tion disclosed.

1 (e) ATTORNEY'S FEES.—In the case of a motion
2 brought under subsection (b) in which the movant has
3 substantially prevailed, the court may assess against the
4 respondent a reasonable attorney's fee and other litigation
5 costs and expenses (including expert's fees) reasonably in-
6 curred.

7 **SEC. 216. SECURITY.**

8 (a) IN GENERAL.—A health information trustee shall
9 maintain reasonable and appropriate administrative, tech-
10 nical, and physical safeguards—

11 (1) to ensure the integrity and confidentiality of
12 protected health information created or received by
13 the trustee; and

14 (2) to protect against any anticipated threats or
15 hazards to the security or integrity of such informa-
16 tion.

17 (b) SPECIFIC SECURITY MEASURES.—The security
18 measures adopted by a health information trustee shall in-
19 clude the following:

20 (1) Officers, employees, and agents of the trust-
21 ee who have access to protected health information
22 created by the trustee shall be regularly trained in
23 the requirements governing such information.

24 (2) Complete, accurate, and readily available
25 records shall be maintained, if the maintenance of

1 such records is practicable, taking into account the
2 technical capabilities of the system used to maintain
3 protected health information and the costs of such
4 maintenance.

5 (3) Appropriate signs and warnings shall be
6 posted to advise of the need to secure protected
7 health information.

8 (c) REGULATIONS.—The Secretary, in consultation
9 with the Attorney General, shall promulgate regulations
10 regarding security measures for protected health informa-
11 tion.

12 **SEC. 217. INSPECTION OF PROTECTED HEALTH INFORMA-**
13 **TION.**

14 (a) INSPECTION OF PROTECTED HEALTH INFORMA-
15 TION.—

16 (1) IN GENERAL.—Except as provided in para-
17 graph (2), a health care provider or health benefit
18 plan—

19 (A) shall permit an individual who is the
20 subject of protected health information to in-
21 spect any such information that the provider or
22 plan maintains;

23 (B) shall permit the individual to have a
24 copy of the information;

1 vidual, except with the authorization of the in-
2 dividual or under compulsion of law.

3 (B) INFORMATION ABOUT OTHERS.—The
4 information relates to an individual other than
5 the individual seeking to inspect or have a copy
6 of the information and the provider or plan de-
7 termines, based on reasonable medical judg-
8 ment, that inspection or copying of the informa-
9 tion would cause sufficient harm to 1 or both
10 of the individuals so as to outweigh the desir-
11 ability of permitting access.

12 (C) ENDANGERMENT TO LIFE OR SAFE-
13 TY.—The provider or plan determines that dis-
14 closure of the information could reasonably be
15 expected to endanger the life or physical safety
16 of any individual.

17 (D) CONFIDENTIAL SOURCE.—The infor-
18 mation identifies or could reasonably lead to the
19 identification of a person (other than a health
20 care provider) who provided information under
21 a promise of confidentiality to a health care
22 provider concerning the individual who is the
23 subject of the information.

24 (E) ADMINISTRATIVE PURPOSES.—The
25 information—

1 (i) is used by the provider or plan
2 solely for administrative purposes and not
3 in the provision of health care to the indi-
4 vidual who is the subject of the informa-
5 tion; and

6 (ii) has not been disclosed by the pro-
7 vider or plan to any other person.

8 (3) INSPECTION AND COPYING OF SEGREGABLE
9 PORTION.—A health care provider or health benefit
10 plan shall permit inspection and copying under para-
11 graph (1) of any reasonably segregable portion of a
12 record after deletion of any portion that is exempt
13 under paragraph (2).

14 (4) CONDITIONS.—A health care provider or
15 health benefit plan may—

16 (A) require a written request for the in-
17 spection and copying of protected health infor-
18 mation under this subsection; and

19 (B) charge a reasonable fee (not greater
20 than the actual cost) for—

21 (i) permitting inspection of informa-
22 tion under this subsection; and

23 (ii) providing a copy of protected
24 health information under this subsection.

1 (5) STATEMENT OF REASONS FOR DENIAL.—If
2 a health care provider or health benefit plan denies
3 a request for inspection or copying under this sub-
4 section, the provider or plan shall provide the indi-
5 vidual who made the request (or the individual's des-
6 ignated representative) with a written statement of
7 the reasons for the denial.

8 (6) DEADLINE.—A health care provider or
9 health benefit plan shall comply with or deny a re-
10 quest for inspection or copying of protected health
11 information under this subsection within the 30-day
12 period beginning on the date on which the provider
13 or plan receives the request.

14 **SEC. 218. AMENDMENT OF PROTECTED HEALTH INFORMA-**
15 **TION.**

16 (a) IN GENERAL.—A health care provider or health
17 benefit plan that is required to comply with this subsection
18 shall, within the 45-day period beginning on the date on
19 which the provider or plan receives from an individual a
20 written request that the provider or plan correct or amend
21 the information—

22 (1) make the correction or amendment re-
23 quested;

24 (2) inform the individual of the correction or
25 amendment that has been made;

1 (3) inform any regional data center to which
2 the uncorrected or unamended portion of the infor-
3 mation was previously disclosed, of the correction or
4 amendment;

5 (4) inform any person who is identified by the
6 individual, who is not an officer, employee or agent,
7 of the provider or plan, and to whom the uncor-
8 rected or unamended portion of the information was
9 previously disclosed, of the correction or amendment
10 that has been made.

11 (b) REFUSAL TO CORRECT.—If the provider or plan
12 refuses to make the corrections, the provider or plan shall
13 inform the individual of—

14 (1) the reasons for the refusal of the provider
15 or plan to make the correction or amendment;

16 (2) any procedures for further review of the re-
17 fusals; and

18 (3) the individual's right to file with the pro-
19 vider or plan a concise statement setting forth the
20 requested correction or amendment and the individ-
21 ual's reasons for disagreeing with the refusal of the
22 provider or plan.

23 (c) BASES FOR REQUEST TO CORRECT OR AMEND.—
24 An individual may request correction or amendment of
25 protected health information about the individual under

1 paragraph (d) if the information is not timely, accurate,
2 relevant to the system of records, or complete.

3 (d) STATEMENT OF DISAGREEMENT.—After an indi-
4 vidual has filed a statement of disagreement under para-
5 graph (b)(3), the provider or plan, in any subsequent dis-
6 closure of the disputed portion of the information—

7 (1) shall include a copy of the individual's
8 statement; and

9 (2) may include a concise statement of the rea-
10 sons of the provider or plan for not making the re-
11 quested correction or amendment.

12 (e) RULE OF CONSTRUCTION.—This subsection shall
13 not be construed to require a health care provider or
14 health benefit plan to conduct a formal, informal, or other
15 hearing or proceeding concerning a request for a correc-
16 tion or amendment to protected health information the
17 provider or plan maintains.

18 (f) CORRECTION.—For purposes of paragraph (2), a
19 correction is deemed to have been made to protected
20 health information when information that is not timely,
21 accurate, relevant to the system of records, or complete
22 is clearly marked as incorrect or when supplementary cor-
23 rect information is made part of the information.

24 (g) NOTICE OF INFORMATION PRACTICES.—

1 (1) PREPARATION OF WRITTEN NOTICE.—A
2 health care provider or health benefit plan shall pre-
3 pare a written notice of information practices de-
4 scribing the following:

5 (A) PERSONAL RIGHTS OF AN INDIVID-
6 UAL.—The rights under this section of an indi-
7 vidual who is the subject of protected health in-
8 formation, including the right to inspect and
9 copy such information and the right to seek
10 amendments to such information, and the pro-
11 cedures for authorizing disclosures of protected
12 health information and for revoking such au-
13 thorizations.

14 (B) PROCEDURES OF PROVIDER OR
15 PLAN.—The procedures established by the pro-
16 vider or plan for the exercise of the rights of in-
17 dividuals about whom protected health informa-
18 tion is maintained.

19 (C) AUTHORIZED DISCLOSURES.—The dis-
20 closures of protected health information that
21 are authorized.

22 (2) DISSEMINATION OF NOTICE.—A health care
23 provider or health benefit plan—

1 (A) shall, upon request, provide any indi-
2 vidual with a copy of the notice of information
3 practices described in paragraph (1); and

4 (B) shall make reasonable efforts to inform
5 individuals in a clear and conspicuous manner
6 of the existence and availability of the notice.

7 (3) MODEL NOTICE.—Not later than July 1,
8 1996, the Secretary, after consultation with the At-
9 torney General and after notice and opportunity for
10 public comment, shall develop and disseminate a
11 model notice of information practices for use by
12 health care providers and health benefit plans under
13 this section.

14 **SEC. 219. ACCOUNTING FOR DISCLOSURES.**

15 (a) IN GENERAL.—A health care provider or health
16 benefit plan that is required to comply with this subsection
17 shall create and maintain, with respect to any protected
18 health information disclosed, a record of—

19 (1) the date and purpose of the disclosure;

20 (2) the name of the person to whom the disclo-
21 sure was made;

22 (3) the address of the person to whom the dis-
23 closure was made or the location to which the disclo-
24 sure was made; and

1 (4) the information disclosed, if the recording of
2 the information disclosed is practicable, taking into
3 account the technical capabilities of the system used
4 to maintain the record and the costs of such mainte-
5 nance.

6 (b) DISCLOSURE RECORD PART OF INFORMATION.—

7 A record created and maintained under paragraph (a)
8 shall be maintained as part of the protected health infor-
9 mation to which the record pertains, except for requests
10 from and disclosures to health oversight agencies.

11 **SEC. 220. STANDARDS FOR ELECTRONIC DOCUMENTS AND**
12 **COMMUNICATIONS.**

13 Not later than July 1, 1996, the Attorney General,
14 in consultation with the Secretary and after notice and
15 opportunity for public comment, shall promulgate stand-
16 ards with respect to the creation, transmission, receipt,
17 and maintenance, in electronic form, of each written docu-
18 ment required or authorized under this title. When a sig-
19 nature is required with respect to a written document
20 under any other provision of this title, such standards
21 shall provide for an electronic substitute that serves the
22 functional equivalent of a signature.

23 **SEC. 221. RIGHTS OF INCOMPETENTS.**

24 (a) EFFECT OF DECLARATION OF INCOMPETENCE.—

25 Except as provided in section 222, if an individual has

1 been declared to be incompetent by a court of competent
2 jurisdiction, the rights of the individual under this section
3 shall be exercised and discharged in the best interests of
4 the individual through an authorized legal representative.

5 (b) NO COURT DECLARATION.—Except as provided
6 in section 222, if a health care provider determines that
7 an individual, who has not been declared to be incom-
8 petent by a court of competent jurisdiction, suffers from
9 a medical condition that prevents the individual from act-
10 ing knowingly or effectively on the individual's own behalf,
11 the right of the individual to authorize disclosure may be
12 exercised and discharged in the best interest of the individ-
13 ual by the individual's next of kin.

14 **SEC. 222. RIGHTS OF MINORS.**

15 (a) INDIVIDUALS WHO ARE 18 OR LEGALLY CAPA-
16 BLE.—In the case of an individual—

17 (1) who is 18 years of age or older, all rights
18 of the individual shall be exercised by the individual;
19 or

20 (2) who, acting alone, has the legal right, as de-
21 termined by State law, to apply for and obtain a
22 type of medical examination, care, or treatment and
23 who has sought such examination, care, or treat-
24 ment, the individual shall exercise all rights of an in-
25 dividual under this title with respect to protected

1 health information relating to such examination,
2 care, or treatment.

3 (b) INDIVIDUALS UNDER 18.—Except as provided in
4 subsection (a)(2), in the case of an individual who is—

5 (1) under 14 years of age, all the individual's
6 rights under this title shall be exercised through the
7 parent or legal guardian of the individual; or

8 (2) 14, 15, 16, or 17 years of age, the rights
9 of inspection and amendment, and the right to au-
10 thorize disclosure of protected health information of
11 the individual may be exercised either by the individ-
12 ual or by the parent or legal guardian of the individ-
13 ual.

14 **SEC. 223. NO LIABILITY FOR PERMISSIBLE DISCLOSURES.**

15 A health information trustee who makes a disclosure
16 of protected health information about an individual that
17 is permitted by this title shall not be liable to the individ-
18 ual for the disclosure under common law.

19 **SEC. 224. NO LIABILITY FOR INSTITUTIONAL REVIEW**
20 **BOARD DETERMINATIONS.**

21 If the members of an institutional review board make
22 a determination in good faith that—

23 (1) a health research project is of sufficient im-
24 portance to outweigh the intrusion into the privacy
25 of an individual; and

1 (2) the effectiveness of the project requires use
2 of protected health information,
3 the members, the board, and the parent institution of the
4 board shall not be liable to the individual as a result of
5 the determination.

6 **SEC. 225. GOOD FAITH RELIANCE ON CERTIFICATION.**

7 A health information trustee who relies in good faith
8 on a certification by a government authority or other per-
9 son and discloses protected health information about an
10 individual in accordance with this title shall not be liable
11 to the individual for such disclosure.

12 **SEC. 226. CIVIL PENALTY.**

13 (a) VIOLATION.—Any health information trustee who
14 the Secretary determines has substantially failed to com-
15 ply with this title shall be subject, in addition to any other
16 penalties that may be prescribed by law, to a civil penalty
17 of not more than \$10,000 for each such violation.

18 (b) PROCEDURES FOR IMPOSITION OF PENALTIES.—
19 Section 1128A of the Social Security Act (42 U.S.C.
20 1320a–7a), other than subsections (a) and (b) and the
21 second sentence of subsection (f) of that section, shall
22 apply to the imposition of a civil monetary penalty under
23 this section in the same manner as such provisions apply
24 with respect to the imposition of a penalty under section
25 1128A of that Act.

1 **SEC. 227. CIVIL ACTION.**

2 (a) IN GENERAL.—An individual who is aggrieved by
3 conduct in violation of this title may bring a civil action
4 to recover—

5 (1) the greater of actual damages or liquidated
6 damages of \$5,000;

7 (2) punitive damages;

8 (3) a reasonable attorney's fee and expenses of
9 litigation;

10 (4) costs of litigation; and

11 (5) such preliminary and equitable relief as the
12 court determines to be appropriate.

13 (b) LIMITATION.—No action may be commenced
14 under this section more than 3 years after the date on
15 which the violation was or should reasonably have been
16 discovered.

17 **SEC. 228. RELATIONSHIP TO OTHER LAWS.**

18 (a) STATE LAW.—Except as provided in subsections
19 (b), (c), and (d), this title preempts any State law to the
20 extent that such law is inconsistent with this title.

21 (b) LAWS RELATING TO PUBLIC HEALTH.—Nothing
22 in this title is intended to preempt or operate to the exclu-
23 sion of any State public health law that prevents or regu-
24 lates disclosure of protected health information otherwise
25 allowed under this Act.

1 (c) PRIVILEGES.—Nothing in this title is intended to
2 preempt or modify State common or statutory law to the
3 extent such law concerns a privilege of a witness or person
4 in a court of the State. This title does not supersede or
5 modify Federal common or statutory law to the extent
6 such law concerns a privilege of a witness or person in
7 a court of the United States.

8 (d) CERTAIN DUTIES UNDER STATE OR FEDERAL
9 LAW.—This title shall not be construed to preempt, super-
10 sede, or modify the operation of—

11 (1) any law that provides for the reporting of
12 vital statistics such as birth or death information;

13 (2) any law requiring the reporting of abuse or
14 neglect information about any individual;

15 (3) subpart II of part E of title XXVI of the
16 Public Health Service Act (relating to notifications
17 of emergency response employees of possible expo-
18 sure to infectious diseases); or

19 (4) any Federal law that prevents or regulates
20 disclosure of protected health information.



Calendar No. 454

103D CONGRESS
2D SESSION
S. 2129

A BILL

To amend title 18, United States Code, to preserve personal privacy with respect to medical records and health care-related information, and for other purposes.

JUNE 7, 1994

Read the second time and placed on the calendar